Early complications of endovenous laser ablation

Konstantin MAZAYSHVILI 1 *, Sergey AKIMOV 2

1Department of Surgery, Surgut State University, Surgut, Russia; 2Vein center “Antireflux”, Zheleznodorozhnyy, Russia

*Corresponding author: Konstantin Mazayshvili, Department of Surgery, Surgut State University, 628403 The 30 Let Pobedy str, 60-59, Surgut, Russia. E-mail: nmspl322@gmail.com

ABSTRACT

Background: The aim of this work was to evaluate the frequency, structure and characteristics of complications after endovenous laser ablation (EVLA).

Methods: The study included 1247 consecutive patients (1417 limbs) with superficial venous insufficiency, treated with EVLA procedures with a wavelength of 1470 nm and automatic pull-back traction of the fiber. Control examinations using Duplex ultrasound were carried out on the second day after EVLA, and in 2 weeks and 1 month after the EVLA procedure. In certain situations, including the detection of complications, timing of the follow-up visits varied.

Results: In the postoperative period (up to 1 month after the procedure) complications were detected in 69 cases (4.87% of the EVLA procedures). Complications included the following: deep vein thrombosis (1.55%), pulmonary embolism (0.07%), pain syndrome (1.41%), abscess (0.07%), seroma (0.21%), fragmentations of the laser fiber (0.14%), hyperpigmentation (0.14%), and burn of the skin (0.07%) of the total number of EVLA procedures.

Conclusions: EVLA is not a unique surgical method of treatment, and it has the same complications as any other surgical intervention. The complications rate in patients was 4.87% of EVLA procedures. Most complications can be avoided by developing a standard regulation on their detection and treatment as early as possible.

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Key words: Laser therapy; Varicose veins; Complications; Venous thrombosis.

There have been many articles in the world literature evaluating the common complications encountered during endovenous laser ablation (EVLA). In 2016, Malgor et al. published the results of the analysis of 349 cases of complications and adverse outcomes of heat-ligation procedure for 12 years. They described thirty cases of non-fatal pulmonary embolism (PE) and 123 cases of deep vein thrombosis (DVT). Also, 7 lethal outcomes were reported directly during the heat-ligation procedure. The cause of death in all cases was PE. In general, within 5 years
an average frequency of complications and adverse outcomes for EVLA was 1:10,000 procedures, in particular: <1:2,500 for DVT, <1:10,000 for PE, and <1:50,000 for lethal outcome.1

Aurshina et al. found thrombotic complication rate 11.4% for EVLA. More frequently there were thrombotic complications in the form of acute superficial thrombosis in the varicosities and their tributaries (4.6%) and EHIT (5.9%). On bivariate analysis, veins with a larger diameter were found to have an increased incidence of acute thrombotic complications.2

Materials and methods

This study was approved by the Institutional Review Board of Surgut University, and the need for consent of individual patients was waived.

Examination and treatment were carried out on an outpatient basis in the 2 vein centers. Evaluation of reflux in the great saphenous vein (GSV) and small saphenous vein (SSV) was performed by Duplex ultrasound.

Before the EVLA procedure, under the ultrasound control, distal border of reflux was marked, varicose veins and incompetent perforating veins were marked. All procedures were performed using laser emitting the light of 1470 nm wavelength and under tumescent anesthesia. The radial fiber tip was positioned (ultrasound guided) at 0.5 cm from the saphenofemoral junction or the saphenopopliteal junction. The tumescent fluid (0.1% Lidocaine) infiltration was ultrasound guided. An average laser power was 6.9 W (5 to 8 W), the speed of automatic pull-back traction of the fiber was constant in all cases -0.75 mm/sec. Simultaneously with EVLA of the great saphenous vein (GSV) or small saphenous vein (SSV), EVLA of 26 perforant veins was performed. In all cases, EVLA was supplemented by simultaneous elimination of varicose dilated tributary veins by mini-phlebectomy using tumescent anesthesia. None of patients were simultaneously treated with sclerotherapy.

After the EVLA procedure, all the patients were recommended a walking tour for 30-40 minutes. The prevention of thromboembolic complications of EVLA with anticoagulants was not routinely performed. All patients were assigned to wear a class II compression stockings (23-32 mmHg) before the first check-up — for 24 hours, then in the daytime for a period of two weeks to two months. Control examinations using duplex ultrasound were carried out on the second day after EVLA, and in 2 weeks and 1 month after the EVLA procedure. In certain situations, including the detection of complications, timing of the follow-up visits varied. The pain syndrome was defined and quantified using Visual Analogue Scale (VAS). Other outcome factors such as hyperpigmentation, ecchymosis, paresthesia were scored from 0 to 3, where 0 was absent, 1 was mild, 2 was moderate and 3 was severe. Patients with a history of venous thrombosis or with previously identified thrombophilia received thromboprophylaxis with anticoagulants for 7 days after EVLA. If after 7 days thrombosis was not detected by ultrasound examination, then anticoagulants were canceled, leaving only class 2 compression stockings.

Statistical analysis

Statistical analysis of the results of the study was performed by using the Student’s t-test and nonparametric criteria of Mann-Whitney and Kolmogorov Test.

Results

Between 2013 and 2017, a total of 1251 consecutive patients underwent EVLA procedures. Of which, 1247 (99.7%) regularly attended the scheduled follow-up visits the next 1 month (1417 lower extremities). Those who did not attend the follow-up visits were excluded from analyses. The analyzed study group consisted of 1051 (84.3%) females and 196 (15.7%) males. In 170 (13.6%) patients, EVLA of the great saphenous veins was performed on both lower extremities. By age categories, the patients were distributed as follows: 17-20 years: 20 (1.6%); 20-35 years: 175 (14%); 35-60 years: 948 (76%); over 60 years: 104 (8.4%). The majority of the operated extremities belonged to the clinical class C2 according to the CEAP classification — 1057 (74.6%). There were almost three times less cases corresponding to C3 class — 324 (22.8%). Trophic changes in form of hyperpigmentation and lipodermatosclerosis were observed in 25 operated lower extremities (1.8%). Only 11 people (0.8%) had an active or healed trophic ulcer (at one limb). All patients had primary varicose veins, i.e. recurrence varicose veins were not included in the study. The extremities on which EVLA was performed were classified according to the clinical classes of CEAP classification as follows (Figure 1).

Elimination of reflux in the GSV was performed in 1253 limbs. An average diameter of GSV before the intervention was 0.7 cm (minimum [0.3 cm], maximum [1.4 cm], and standard deviation [0.16]). Elimination of reflux in the SSV was performed in 164 limbs. An average diameter of SSV was 0.6 cm [minimum [0.3 cm], maximum [1.2 cm],...
included: 5 EHIT, 14 sural veins thrombosis (3 symptomatic and 11 asymptomatic), 2 popliteal vein thrombosis and 1 symptomatic femoral vein thrombosis. One patient in two symptomatic popliteal vein thrombosis developed symptomatic PE. Among the patients in whom the EVLA procedure was complicated by DVT, there were 7 men, 15 women. Of these, thrombosis occurred in 18 cases of EVLA GSV, in 4 cases after EVLA SSV. Following the EVLA procedure, DVT often developed on the left lower extremity (14 cases), while on the right lower extremity, DVT developed in 8 cases. The average age of patients with DVT after EVLA was 53.6 years.

Significantly more often (P<0.05) DVT after EVLA occurred on the limbs with classes C3-C6 (8 of 358 or 2.2%) in comparison with clinical class C2 according to CEAP classification (14 limbs out of 1057, or 1.3%). Figure 2 presents the data on DVT cases following EVLA.

The majority of DVT after EVLA occurred in a zone remote from the coagulation area. After GSV EVLA, it happened in 14 patients (Figure 2). Most often, DVT was detected during a follow-up examination in 14 days after the EVLA procedure. In two cases DVT was detected on day 7 after the surgery, as patients noted discomfort in the shin of the operated limb and consulted an attending physician before the scheduled follow-up examination. It is noteworthy that in 4 (out of 22) patients thrombosis occurred on the limb where EVLA was performed after a short period (2 weeks) following the EVLA procedure on the opposite leg.

Endothermal heat-induced thromboses (EHIT) of SFJ of class ≥2 by L.S. Kabnick\(^3\) occurred in 5 cases (0.4% and standard deviation [-0.16]). There were no patients that had same leg GSV and SSV reflux treated.

As a result of observation in the postoperative period (up to 1 month), complications were revealed in 69 patients (4.87% of EVLA procedures, Table I). Complications included the following: DVT (1.55%), PE (0.07%), pain syndrome (1.41%), paresthesia (1.06%), abscess (0.07%), and seroma (0.21%), fragmentation of the tip of the radial fiber (0.14%), fiber fragmentation (0.14%), hyperpigmentation (0.14%), and skin burn (0.07%) of the total number of procedures.

Ecchymoses and sensation of “chorda” in the projection of the GSV are related to minor complications of EVLA. From our point of view, ecchymoses are normal manifestation of EVLA, since they did not affect the patients’ well-being and ability to work, and did not require treatment.

**Deep vein thrombosis**

This complication occurred in 22 patients (22 operated extremities, 1.55% of all EVLA cases). These complications...
of all EVLA procedures performed). Of these, there were three EHIT class 2 and one EHIT class 3 by Kabnick after GSV EVLA, and one case after SSV EVLA (class 2 by Kabnick). In all cases of EHIT, the diameter of the coagulated vein was more than 8 mm at the level of the saphenofemoral junction (SFJ). According to our data, the proportion of EHIT in the structure of all DVT cases after EVLA was 22.8% (Figure 2). Identification of EHIT in four cases out of five occurred at the first follow-up examination (on day 2 after the EVLA procedure). In 4 cases of EHIT class 2 by Kabnick we prescribed compression therapy and anticoagulants for a period of 7 to 14 days, until the complete lysis of the thrombus. Long-term anticoagulant therapy within 3 months after EVLA was necessary only in one case (EHIT, class 3 by Kabnick).

We also noted 1 case (0.07% of all EVLA cases) of a PE in a patient after EVLA with a history of DVT on the operated leg. The patient does not remember the episode of DVT. However, ultrasound examination before the operation in the popliteal vein revealed the changes characteristic of postthrombotic syndrome. Complication developed three weeks after EVLA and required hospitalization of the patient in the hospital and adequate therapy.

The second frequent complication of EVLA was the pain syndrome along the vein after 1.41% of the EVLA performed, in 17 out of 20 cases after GSV EVLA. It was most likely connected with a low pain threshold of patients. In such cases, we have prescribed non-steroidal anti-inflammatory drugs in standard dosages for up to 10 days.

In our practice, 15 cases of paresthesia (1.06% of the EVLA procedures) were observed, in all cases of GSV EVLA. Sensitivity disorders were localized in the lower third of the thigh along the medial surface (in the projection of the coagulated vein). No special treatment was performed, at the follow-up examination in 2 months after EVLA, patients did not complain about sensitivity disorders.

**Phlegmonous phlebitis**

This complication was encountered in our practice once (0.07% of all EVLA cases). On the fifth postoperative day, the treated leg showed clear evidence of diffuse infection and a radical debridement with extensive drainage was undertaken, after which recovery occurred. Culture of a swab revealed infection with Staphylococcus aureus, and histology of the ablated SSV showed acute thrombophlebitis.

In several cases, we detected a congestion of serous effusion in the subcutaneous tissue, seroma (0.21% of EVLA cases). Seroma in the operation area was detected on day 2 after surgical treatment. No special treatment was required. The contents of seroma were evacuated by puncture under ultrasound control, a pressure bandage was applied with subsequent application of class II compression stockings. In all cases the complete regression of this complication was noted by the end of the first month of observation after EVLA.

**Fragmentation of the tip of the radial fiber**

In our practice, there were two such cases (0.14% of EVLA cases). In both cases, crossectomy and removal of fragments of the fiber tip was performed.

Fragmentation along the course of the fiber in vein occurred twice in our practice (0.14% of EVLA cases). Another complication of EVLA — hyperpigmentation — was noted in two patients (0.14% of all EVLA cases) in the projection of the coagulated superfascial segment of GSV in the distal femur. Both patients were middle-aged, without excess body weight, and had class C2 according to CEAP. Hyperpigmentation did not affect the outcome of the treatment but caused aesthetic discomfort to the patients. During the follow-up examination 6 months after EVLA, in both cases hyperpigmentation of the skin disappeared.

Skin burn is the rarest (0.07% of EVLA cases) among the occurred complications. This complication developed because of the lack of continuous ultrasound monitoring of the EVLA process.

Allergy on anesthetic (lidocaine) did not occur in our practice. Twice we observed cases of convulsive syndrome with short-term loss of consciousness. In the first case, convulsive syndrome developed when performing tumescent anesthesia, after administration of 200 mL of 0.1% lidocaine solution. The second case was associated with psychoemotional factor, as convulsions with short-term loss of consciousness developed in the patient who stayed in the operating room on the surgical table before carrying out any manipulation.

**Discussion**

In our study, the frequency of DVT was 1.55%. Chaar et al.\(^4\) pointed out a large diameter of vein (>1.0 cm) among the risk factors for DVT development after EVLA. We did not find a statistically significant predictor of DVT in this study. EHIT is a specific complication for thermal ablation methods, in particular for EVLA. The frequency of EHIT development after EVLA according to the literature data...
is 0.9% - 40.1%. In scientific publications, one can find data on risk factors for the development of EHIT; they include the following: a prior history of DVT,^3 configuration of sapheno-popliteal junction,^8 large GSV diameter,^9 male sex, high risk of DVT according to Caprini Scale,^10 size of the vein, age, large volume of operation.\textsuperscript{11}

The frequency of pain syndrome, according to the literature, is very variable and can achieve 43%.\textsuperscript{12} It depends on the period of examination after EVLA and the method of assessing the intensity of the pain syndrome. In our study, the incidence of pain syndrome was 1.41%.

Sensitivity disorder in the area of the coagulated vein is one of the stochastic complications specific for EVLA. Paresthesia, according to the literature, is found in 1.8%.\textsuperscript{13} In our study, paresthesias developed in 1.06% of the EVLA performed.

In rare cases, the formation of serous exudate in the field of EVLA is possible. Sometimes it requires removal,\textsuperscript{14} and in some cases, suppuration develops.\textsuperscript{15} In these situations, attention is paid to the localization of inflammation: suppuration can be occurred not in the place of puncture of the skin. In our practice, there was one case of phlegmonous phlebitis formation and three cases of seroma formation in the EVLA zone (0.07% and 0.21% of the procedures performed, respectively).

As in case of any endovascular intervention, EVLA is always accompanied by complications in form of intravascular foreign body, for example, fracture of a part of the fiber or fragmentation of the tip of a radial fiber. Such cases of intraoperative fragmentation of the fiber are not that rare; they are described the literature.\textsuperscript{16, 17} In our practice, each of these complications occurred 2 times (0.14% of the EVLA procedures). In one case, the end-face fiber was damaged by a needle during the anesthesia. A fragment 6-cm long was removed through a puncture of the skin in the projection of the coagulated GSV. Analysis of these cases shows the necessity for strict visual control of the position of the tip of the puncture needle with respect to the wall of the vein. The more additional manipulations or devices we use during surgery, the higher is the risk of such complications.

Hyperpigmentation in the projection of the coagulated vein, according to the literature, occurs with a frequency near of 5%.\textsuperscript{18} As a rule, this happens in case of EVLA of the suprafascial segments of the vein. In our practice, hyperpigmentation occurred in two cases of GSV EVLA — 0.14% of all procedures performed.

Single case reports of burns in patients after EVLA have been published.\textsuperscript{19} Almost always this was caused by an error in the technique of intervention. In our work, the incidence of skin burn after EVLA was 0.07%, which does not exceed the global values.

**Conclusions**

EVLA is not a unique surgical method of treatment, and it has the same complications as any other surgical intervention. The complications rate in patients was 4.87% of EVLA procedures. Most complications can be avoided by developing a standard regulation on their detection and treatment as early as possible.

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Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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